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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,433	04/20/2001	Claude Jarkae Jensen	10209.56	1737

21999 7590 11/01/2004

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,433

Applicant(s)

JENSEN ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 8, 11 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-8, 11, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Request for Reconsideration received August 23, 2004 is acknowledged. Claims 1, 7-8, 11-12, 22, and 27 are pending in this application. Claims 2-6, 9-10, 13-21, and 28-30 stand cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1, 7-8, 11, and 27 are under 35 U.S.C. 103(a) as being unpatentable over JP2000-095663 to Kondo et al by itself or in view of Elkins (Hawaiian Noni, 1998) is maintained.

JP teaches a plant extract such as *Morinda citrifolia* for external use. These plant extracts have various properties such as skin whitening abilities, antioxidants effects, and antimicrobial effects, which make them effective for external use. See abstract. The plant extract is utilized in the amount of 0.0005-5% and JP discloses the use of instant *Morinda citrifolia* in the amount of 4.8%. Note Table 2 and page 4 of the translation. The plant extract is extracted from the branch, trunk, bark, bloom, fruit, roots, or other dry matters. The fruit is exemplified. See page 3. The external applications taught are milky lotion, cream, a pack, foundation, lipstick, shampoo, and conditioner and in the form of a liquid, salve, gel, etc. See page 2 and examples. Kondo et al teach additives such as lower alcohols, polyhydric alcohols, oily components (paraffin, squalene, cetyl alcohol), antioxidants, surfactants, thickeners, astringents, UV absorbents (octyl

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methoxycinnamate), vitamins, etc. in the cosmetic compositions. See examples and page 4.

Examples teach the instant additives. It should be noted that linoleic acid and xeronine are inherent properties of *Morinda citrifolia*.

JP does not specify the part of the fruit utilized, i.e. the fruit seed oil or the fruit juice.

Elkins teaches the usage of noni for over hundreds of years for its therapeutic actions (antimicrobial, antioxidant, and emollient benefits). Elkins teaches that *all* parts of the noni plant such as the fruit, the seeds, bark, leaves, and flowers are utilized. See page 9-11. One of the most prevalent uses of noni is as a skin healing agent due to the presence of proxeronine and the skin's response to it. See page 30.

Although, JP does not specify the part of the *Morinda citrifolia* fruit utilized, it is deemed obvious to one of ordinary skill in the art to utilize any part of the *Morinda citrifolia* extract in the cosmetic composition. One would have been motivated to do so since JP teaches any part of the plant may be utilized and it will have the cosmetic benefits of skin whitening abilities, antioxidants effects, and antimicrobial effects. Therefore, one would be motivated to utilize the fruit juice and oil for an additive effect.

Furthermore, one would look to the teachings of the prior art, i.e. Hawaiian Noni and its uses of noni, and note that all the parts of the noni plant provide beneficial effects to the skin. Therefore, one would have been motivated to combine the various plant parts and expect an additive effect on the skin.

In regards to claim 11, one would be motivated to manipulate the concentration of the additive depending on the desired form, i.e. a cream, salve, stick, or ointment, of the cosmetic. This is viewed as a manipulatable parameter known to those skilled in the art.

Response to Arguments

Applicant's arguments filed 8/23/04 have been fully considered but they are not persuasive.

Applicant argues that neither reference teach all the limitations, in particular the weight percent of the oil and fruit juice respectively. Applicant teaches that Kondo (JP '663) does not teach the particular combination of noni oil and fruit juice. Applicant argues that Kondo teaches away from *Morinda citrifolia* and the exclusive use of it. Lastly, applicant argues that the instant claims are directed to a lip treatment and Kondo teaches all other forms of cosmetics.

Applicant argues that the secondary reference, Elkins, does not cure the deficiencies in Kondo. Applicant argues that Elkins does not teach the specific use of noni oil and fruit juice nor does Elkin teach the use of *Morinda citrifolia* for lip care.

Firstly, the examiner points out that in response to applicant's arguments, the recitation "lip treatment" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In instant case, the preamble does not provide a structural limitation to complete the body of the claims; rather it serves as an intended use phrase. It should be noted a recitation of the intended use of the claimed invention is not given patentable weight unless it provides for a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

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invention from the prior art. In the instant case, the prior art structure is capable of performing the intended use, thus it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Secondly, the examiner points out that Kondo in fact, does teach the use of *Morinda citrifolia* in a lipstick form on page 2.

With regard to the weight percent of the extract, the examiner points out that Kondo teaches the use of the extract in an amount of 0.0005-5%, which falls within the claimed range.

With regard to the argument that the instant invention is exclusively made of the extract (oil and juice), the examiner points out that the applicant is relying on features that are not claimed. The instant claims language is open to other components in the formulation. Moreover, the dependent claims require additives in the range of 20-80%. Therefore, this argument is perplexing since the claims also utilize and require conventional additives like Kondo and is not made of the extract exclusively.

The examiner recognizes that Kondo does not specify the instant combination and thus the rejection is made under obviousness. However, Kondo does not provide adequate motivation to utilize all parts of the plant and most preferably the fruit. The examiner points out that the fruit contains both the fruit juice and the seeds containing the oil.

The examiner relies on the secondary reference to teach the conventional use of all parts of the plant without distinction, for medicinal purposes including the use of *Morinda citrifolia* for skin healing purposes since it has emollient benefits.

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Absent the unexpectedness of using the instant combination in the instant weight ratio, the examiner maintains the rejection since Elkins clearly teaches the state of the art wherein all parts of the noni plant have been used for many years prior to the instant invention.

The rejection of claims 11-12 and 22 are under 35 U.S.C. 103(a) as being unpatentable over JP2000-095663 to Kondo et al by itself or in view of Elkins (Hawaiian Noni, 1998) in further view of Lane (5,503,825) is maintained.

JP teaches a plant extract such as Morinda citrifolia for external use. These plant extracts have various properties such as skin whitening abilities, antioxidants effects, and antimicrobial effects, which make them effective for external use. See abstract. The plant extract is utilized in the amount of 0.0005-5% and JP discloses the use of instant Morinda citrifolia in the amount of 4.8%. Note Table 2 and page 4 of the translation. The plant extract is extracted from the branch, trunk, bark, bloom, fruit, roots, or other dry matters. See page 3. The external applications taught are milky lotion, cream, a pack, foundation, lipstick, shampoo, and conditioner. See page 2. Kondo et al teach additives such as lower alcohols, polyhydric alcohols, oily components, antioxidants, surfactants, thickeners, astringents, UV absorbents, vitamins, etc. in the cosmetic compositions. See examples and page 4. Examples teach the instant additives.

*It should be noted that linoleic acid and xeronine are inherent properties of Morinda citrifolia.

Elkins teaches the usage of noni for over hundreds of years for its therapeutic actions (antimicrobial, antioxidant, and emollient benefits). Elkins teaches that all parts of the noni plant such as the fruit, the seeds, bark, leaves, and flowers are utilized. See page 9-11. One of the most prevalent uses of noni is as a skin healing agent due to the presence of proxeronine and the skin's response to it. See page 30.

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JP does not specify the instant additives (ozokerite) or the concentration of the white petrolatum.

Lane teaches a lip balm composition containing aloe and salt. Lane teaches conventional additives and vehicles for the inventive aloe/salt component. These conventional additives are petroleum, silicon oils, paraffin, beeswax, ozokerite, cetyl alcohol, isopropyl myristate, fatty acids, UV absorbers such as salicylic acid derivatives, derivatives of cinnamic acids, and benzophenone derivatives (col. 4, lines 15-62) and the form may be stick, salve, cream, or ointment. Example 2 teaches a lip balm base that contains 44% petrolatums, 0.1% lanolin, 0.5% cetyl alcohol, 1.5% padimate, and 1% isopropyl myristate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Lane and utilize the instant additives and concentrations. One would have been motivated to do since Lane teaches a conventional lip balm base known in the art and utilizes the *conventional* lip balm base with the inventive aloe/salt component. Therefore, although Kondo et al teach a lipstick composition but do not exemplify a lipstick, one would be motivated to look to the prior art and utilize a conventional lip base in combination with the “inventive concept”, i.e. the extract, with the expectation of similar results.

Response to Arguments

Applicant's arguments filed 8/23/04 have been fully considered but they are not persuasive.

Applicant argues that Lane does not teach the use of noni in the lip balm.

Firstly, it is pointed out that the applicant is attacking the individual references to show unobviousness wherein the rejection is based on a *combination* of references. See *In re Young*,

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403 F.2d 754, 757, 159, USPQ 725, 728 (CCPA 1968). Moreover the test for obviousness is not that only one reference expressly teaches the claimed invention, rather the test is what the combined teachings would have suggested to a skilled artisan. See *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

In instant case, Lane need not teach the instant extract since the primary reference teaches this limitation. Lane is relied upon to teach the conventional lip base wherein Lane clearly states that a conventional lip base is used with her inventive concept of aloe and salt. The motivation to look to Lane conventional lip base stems from Kondo's suggestion of using the noni extract in a lipstick form.

Therefore, the rejection is maintained.

The rejection of claims 1, 7-8, 11, and 27 are under 35 U.S.C. 103(a) as being unpatentable over Tahitian Noni Products (<http://www.noni-now.com>, copyright 1998-2003) by itself or in view of JP2000-095663 to Kondo et al is maintained.

Tahitian Noni discloses that noni (*Morinda citrifolia*) products combine the benefits of Tahitian noni juice and Tahitian noni oil that nourishes the skin at the cellular level. The cite states that the noni juice delivers soothing and renewing benefits to the skin and the oil contains linoleic acid and essential fatty acids to nourish the skin and dry spots (Note Tahitian Noni essential oil). The reference teaches an SPF lip balm containing noni oil. Lastly, the reference teaches the combination of the juice and oil in Tahitian Noni Skin Supplement and Body Balance Cream.

The reference does specify percentages in the topical formulation.

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JP teaches a plant extract such as *Morinda citrifolia* for external use. These plant extracts have various properties such as skin whitening abilities, antioxidants effects, and antimicrobial effects, which make them effective for external use. See abstract. The plant extract is utilized in the amount of 0.0005-5% and JP discloses the use of instant *Morinda citrifolia* in the amount of 4.8%. Note Table 2 and page 4 of the translation. The plant extract is extracted from the branch, trunk, bark, bloom, fruit, roots, or other dry matters. See page 3. The external applications taught are milky lotion, cream, a pack, foundation, lipstick, shampoo, and conditioner. See page 2.

Although the Noni products fail to disclose the amount of the *Morinda citrifolia* juice and oil, the mere difference in concentration as the sole criteria for patentability for subject matter encompassed by the prior art is not supported in the absence of unexpected data. See MPEP 2144.05. Furthermore, since the Noni lip balm contains the same critical ingredients for the same functional purpose and absent the applicant's demonstration of the criticality to the concentration of the components, it is deemed that concentration is a manipulatable parameter known to those skilled in the art at the time the invention was made.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teaching of Kondo et al and utilize the instant range of the *Morinda citrifolia*. One would have been motivated to do so since Kondo et al teach cosmetics such as a lipstick or face cream containing *Morinda citrifolia* in the instant range. Further, Kondo teaches the medicinal extract is obtained from any part of the plant. Thus, one would have been motivated to utilize the instant range with the expectation of similar results.

Response to Arguments

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Applicant argues that the Tahitian Noni Advertisement fails to disclose or suggest any particular components of the suggested lip balm. Applicant argues that the body Balance Cream in the Advertisement does not render the instant invention obvious since the formulation is not for the lips. It is argued that “lips are not really skin” and thus skin products are not suited for the skin.

Applicant's arguments have been fully considered but they are not persuasive. It should be first noted that “lip balm” is a preamble has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It should also be noted that although there are differences between the skin and lips, the examiner points out that the lips are classified as skin made of epidermis and the dermis. In determination of non-analogous art, the examiner considers factors such as, the prior art teaches a non-toxic composition for topical application. Additionally, the composition is applied to the epidermis to moisturize it. Thus, it is quite reasonable to assert that the references utilized by the examiner are analogous art. It also should be noted for the record that Tahitian Noni does in fact specifically teach a lip balm. Further, the examiner notes that the website that has been cited by applicant is nonexistent.

Secondly, the examiner points out that the website Advertisement clearly states, “Morinda proprietary formula combines the benefits of the raw Tahitian Noni Juice and Tahitian

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Noni oil.” Therefore, the components of the cosmetic composition such as the lip balm and body balance cream are given. The only deficiency of the prior art is the concentration and absent the criticality of applicant’s range, it is deemed an obvious parameter since the prior art composition are utilized for same purpose as applicant: a topical application for moisturizing the skin.

Lastly, it should be noted that applicant does not provide any unexpected results to patentably distinguish the instant invention for Noni products.

For the reasons stated above, the rejection is maintained.

The rejection claims of 1, 7-8, 11-12, 22, and 27 are under 35 U.S.C. 103(a) as being unpatentable over Tahitian Noni Products (<http://www.noni-now.com>, copyright 1998-2003) in view of Pelle et al (6,136,301) is maintained.

Tahitian Noni discloses that noni products combine the benefits of Tahitian noni juice and Tahitian noni oil that nourishes the skin at the cellular level. The cite states that the noni juice delivers soothing and renewing benefits to the skin and the oil contains linoleic acid and essential fatty acids to nourish the skin and dry spots (Note Tahitian Noni essential oil). The reference teaches an SPF lip balm containing noni oil. Lastly, the reference teaches the combination of the juice and oil in Tahitian Noni Skin Supplement and Body Balance Cream.

The reference does specify percentages in the topical formulation.

Pelle et al teach a natural lip product for repairing chapped, cracked lips (col. 1, lines 10-25). Pelle teaches the use of free fatty acids (5-40%) such as oleic and palmitic acid since these are the primary naturally occurring free fatty acids in the stratum corneum (col. 3, lines 40-56). A wax base “known in the art” is formulated from waxes and oils. Waxes such as beeswax, ozokerite or paraffin and plant or animal oils are taught in the amount of 1-20% (col. 4, lines 38-

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41). Sunscreens such as zinc oxide are taught. See column 5, line 1. Pelle teaches the use of active agents such as anti-irritants in the composition (col. 5, line 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Tahitian Noni Products and Pelle et al and use the instant range. One would be motivated to look at the teachings of Pelle since Pelle et al provide the general guidance in formulating a moisturizing lip product with essential oils. Pelle teaches using natural oils containing essential fatty acids in the instant amount and Tahitian Noni teaches noni heals, soothes, and nourishes the skin and the oil contains fatty acids such as oleic and palmitic acids. Therefore, one would expect similar results using the instant range since both references teach moisturizing lip formulations with essential fatty acids.

Although the Noni products fail to disclose the amount of the *Morinda citrifolia* juice and oil, the mere difference in concentration as the sole criteria for patentability for subject matter encompassed by the prior art is not supported in the absence of unexpected data. See MPEP 2144.05.

Response to Arguments

Applicant does not address Pelle et al specifically and argues the merits of Tahitian Noni. The arguments pertaining to Tahitian Noni have been addressed above. It should be noted that applicant does not provide any unexpected results to patentably distinguish the instant invention for Noni products.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

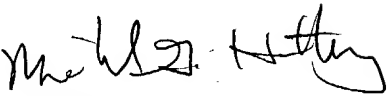
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616


MICHAEL G. HARTLEY
PRIMARY EXAMINER